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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,308	07/29/2003	Zhong Zhang	TPIP018	6429

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
07/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,308	ZHANG ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,8,9,11,12 and 25-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,8,9,11,12 and 25-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/5/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/18/09 has been entered.

2. Applicant's arguments filed 5/4/09 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 6, 8-9, 11-12 and 25-29 are pending. Claims 28-29 are newly added. Claims 1, 9, 12 and 25 are amended.

5. The rejection of Claims 1, 6, 8-9, 11-12 and 25-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn due to the amendment of the claims.

6. The rejection of Claims 1, 6, 8-9, 11-12 and 25-26 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn due to the amendment of the claims.

7. The rejection of claims 1, 6 and 8-9, 11-12 under 35 U.S.C. 103(a) as being unpatentable over Glen et al US 4,452,817 in view of Meadow US 7,166,303 is withdrawn because of the newly applied prior art below. Applicant's arguments with respect to claims 1, 6 and 8-9, 11-12 have been considered but are moot in view of the new ground(s) of rejection.

8. The rejection of claims 1, 6 and 8-9, 11-12 and 25-26 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 17-50 of U.S. Patent Application No. 10/677,747 is withdrawn because the application is abandoned.

9. Claims 1, 6, 8-9, 11-12 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 6,743,436) in view of Glen (US 4,452,817) and as evidence by Dennis et al. (US 6,623,765).

Lee et al. teach an intravenous injection composition (i.e., intrinsically sterile) comprising 1 % propofol, 8% poloxamer 188 and 5% polyethylene glycol 400 (as it relates to claims 1, 6, and 25; see Example 7, col. 7, lines 32-45) that is thermodynamically stable (see col. 5, lines 13-15) and is "transparent", thus clear to the naked eye (see col. 5, lines 15-20 as it relates to claim 1). Lee also teaches the

composition typically has a particle size diameter of 100 nm (as in instant claim 8, see also col. 4, lines 49-52 and col. 5, lines 40-43) wherein the composition comprising propofol does not support microbial growth (see col. 7, lines 40-45, as required by claims 1 and 9) and is stable (see col. 5, lines 13-15). Because Lee does not teach the addition of propylene glycol and lipid, the composition intrinsically comprises "less than 1%" lipid and 0-1% propylene glycol (as required by instant claims 1 and 25). Since the agents of Lee and the agents required by instant claim 1 are identical, it is assumed that in a 100 ml stable composition comprising propofol (1%), poloxamer 188, and polyethylene glycol would comprise less than 5% propofol degradants when maintained at 40°C for 4 weeks (see col. 5, lines 13-15).

Lee also teaches the composition may further comprise a surfactant (see example 7), a tonicity modifier glycerol (as required by instant claim 11, see col. 3, lines 52-55), and a base sodium hydroxide (see col. 5, lines 33-35).

With regards to instant claim 27, Lee teaches the sterile solution is placed into a suitable container and sealed. Intrinsically, it is capable of being dispensed as needed (i.e., as it relates to claim 27). Lee also teaches that it is known in the art to add EDTA to the composition as a preservative as required by instant claim 6 (see col. 2, lines 40-43).

However Lee fails to teach the specific percentages of polyethylene glycol 400 and the required temperature of 40°C (as required by instant claim 1, 25 and 26). Lee also fails to teach the addition of propylene glycol as required by instant claim 26, and specific excipients such as citric acid as required by instant claims 28-29. Nonetheless,

Lee teaches concentrations of polyethylene glycol may vary from 0.5% to 5% as exemplified in examples 6-8 at col. 7.

Glen et al. teach an aqueous formulation comprising 2, 6-diisopropylphenol (propofol) at 1-2 % (see col. 7 lines 17-24) and a block-copolymer PLURONIC F68 (i.e., Poloxamer 188 or P188) in the range of 2-30%, and PEG in the range of 2-30% (as in claims 1 and 25). Glen also teaches that the composition further comprises citric acid in the amount of 1% (as required by instant claims 28 and 29; see col. 3, lines 7-10 and col. 4, lines 51-52). It should be noted that this formulation of Glen is free of propylene glycol (i.e., 0-1%) as required by claims 1 and 25. The formulation further does not support microbial growth as it comprises an antimicrobial excipient (sodium metabisulfate) (see col. 3, lines 3; as required by instant claim 9). As to instant claim 8, the agents or compounds are the same as that claimed. Therefore it is reasonable that particle size is an inherent property of the agent; absent evidence to the contrary.

However, Glen fails to teach the addition of 1% propylene glycol as required by instant claim 26. Nonetheless Glen also teaches amounts of propylene glycol may be from 5-20% in their other embodiments (see col. 3, lines 29-30).

One of ordinary skill in the art would have been motivated to modify the teachings of Lee by adding citric acid to the composition to help maintain a physiological pH (as a buffering agent) and because citric acid is well known in the art to be capable of stabilizing pharmaceutical solutions as a chelating agent.

Even though Glen is silent in as to what temperature is used, one of ordinary skill in the art would be motivated to store the propofol composition at an ambient room temperature (i.e., 37-40°C, as it relates to claim 1).

Even though Lee fails to teach the addition of propylene glycol to the propofol composition, Glen teaches that propylene glycol may be added to compositions of propofol. As evidence by Dennis et al, the solubility of non-polar drugs can be significantly increased when dissolved in propylene glycol by influencing the hydrophobic forces in the system (see col. 8, lines 11-15). Therefore, since propofol is poorly soluble in water, one of ordinary skill in the art would have been motivated to add propylene glycol to a pharmaceutical formulation to resolve any undissolved propofol particle in the composition.

10. Claims 1, 6 and 8-9, 11-12 and 25-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-47 of (U.S. Patent 7,550,155).

Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of the patent '155 are to an aqueous formulation comprising 1% propofol and excipients up to 15% and the claims of the instant application are also drawn to a sterile aqueous pharmaceutical composition comprising 1% propofol and excipients up to 15%, wherein the excipients are the same as the patented '155 claims.

Both sets of claims recite using the same compositions and/or derivatives thereof. See current application claims 1, 6 and 8-9, 11-12 and 25-29 and patented claims 1-50.

In view of the foregoing, the copending application claims and the current application claims are obvious variations of each other.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618

/Robert C. Hayes/
Primary Examiner, Art Unit 1649